K001329

FEB 1 4 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS FOR LIFEMED OF CALIFORNIA IV SETS

Submission Information:

Submitted By: Lifemed of California
2059 Del Amo Blvd.
Rancho Dominguez, CA 90220-6131

Contact Person: Patricia Brinker
Vice President of Quality Assurance
(310) 638-6167

Submitted On: April 26, 2000

Device Information:

Trade Name: (Trade Name) IV Set
(Trade Name) IV Set with Burette
(Trade Name) Extension Set

Common Name: IV Administration Set
Classification Name: Set, Administration, Intravascular

Equivalent Devices:
Nipro Disposable Solution Infusion Set
B. Braun (McGaw) IV Administration Set
B. Braun Measured Volume Solution IV Administration Set
Abbott In Line Burette Set 150
Abbott IV Extension Set SL

Device Description:
The IV Set is a single use, sterile, nonpyrogenic device sterilized with Ethylene Oxide gas. The set is used to administer fluids from an IV container to a patient's vascular system.

The Extension Set will provide an extension to increase the length of an IV set or a syringe. The set is used to administer fluids from an IV container or a syringe to a patient's vascular system.

We will offer both standard sets and custom sets to meet customer specifications. The device is composed of tubing in various lengths and sizes and may include one or more of the following: vented or nonvented, hollow spike to penetrate and connect the tubing to the fluid container, burette chamber with an automatic shut off diaphragm, drip chamber with or without a filter, a drop former, injection site, Y connector to join multiple lines to allow multiple solutions to be administered, stopcock, tubing and components connected to the stopcock, male luer, female luer, needle, flashbulb, cap and clamp.

Intended Use:
The IV Set is a single use, sterile, nonpyrogenic device that is used to administer solutions from an IV container into a patient's vascular system or into another set. The IV Set with Burette is used to provide a measured fluid volume. The Extension Set provides an extension to increase the length of an IV Set or a syringe.

Technological characteristics:
There are not any new technological characteristics when compared to the Equivalent Devices.

Performance Data:
No performance standards are required by Section 514.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2001

Ms. Patricia Brinker
Vice President of Quality Assurance
Lifemed of California
1216 South Allec Street
Anaheim, California 92805

Re: K001329
Trade Name: IV Sets, IV Sets with Burette, Extension Sets
Regulatory Class: II
Product Code: FPA
Dated: December 20, 2000
Received: December 21, 2000

Dear Ms. Brinker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number: K001329

Device Name: IV Sets, IV Sets with Burette, Extension Sets

Indications for Use: All three types of devices are single use, sterile and nonpyrogenic. The IV Set is used to administer fluids from an IV container into a patient's vascular system or into another set. The IV Set with Burette is used to supply a measured fluid volume into a patient's vascular system or into another set. The Extension Set is attached to the end of an IV Set. It provides an extension to increase the length of an IV Set to allow the administration of fluids into a patient's vascular system or into another set.

The administration of fluids into another set may be performed for the following reason: the Lifemed set may act as a secondary set to administer additional solution through a primary IV set. This is commonly called a piggy-back method. The primary set is the main set and is the only set directly attached to the patient. All other sets that attach to the primary set are called secondary sets.

Patricia Cucenti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001329